

### **REMARKS**

Claims 7-12 and 14-29 are pending herein. By this Amendment, Claims 1-3 and 5-6 are canceled without prejudice or disclaimer; Claims 7, 14-18, and 22-23 are amended; and new Claims 24-29 are added.

Support for the claim amendments and new claims is found in the specification at, *inter alia*, paragraphs [0036], [0039], [0043], [0045]-[0047], [0049]-[0051], [0059], [0064]-[0065], [0078], and [0084]. No new matter is added by this Amendment.

Applicant respectfully requests an interview prior to the Examiner acting upon the present Amendment and his representative will call Examiner Lin to discuss scheduling the interview.

#### **I. REJOINDER**

Applicants respectfully request rejoinder of withdrawn Claims 7-12, 14, and 17 upon allowance of the pending claims.

#### **II. FORMAL MATTERS**

Claims 1, 3, 5-6, 15-16, and 18-23 were rejected under 35 U.S.C. 112, first paragraph, as assertedly being non-enabled. This rejection is respectfully traversed.

According to the present invention, if rodents at a contaminated site have impaired reproductive capability as determined by exceedances of sperm parameter benchmarks, then by implication, other mammals, have the potential to be experiencing similar reduced reproductive success. Rodents are the “perfect real-world, worst-case receptors of exposure” because they burrow in the contaminated soil, eat contaminated vegetation, and drink contaminated water. They typically do not migrate and many generations of rodents live in contaminated areas year after year. See specification at paragraph [0036]. Based upon the results of the claimed Rodent Sperm Analysis (RSA), results can be extrapolated for other receptors, for example, regarding their contact with the ground and foraging (paragraph [0051]).

Attached hereto is a Declaration Under 37 CFR 1.131 and 1.132 to demonstrate that the present application is enabled in view of the knowledge of one of ordinary skill in the art and the cited article Working, *Male Reproductive Toxicology: Comparison of the Human to Animal Models*, Environmental Health Perspectives, Vol. 77, 37-44 (1988).

One of ordinary skill in the art would be able to practice the claimed invention without undue experimentation. The pending claims are enabled and the requirements of 35 U.S.C. 112, first paragraph, are satisfied. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 3, 5-6, 15-16, and 18-23 were rejected under 35 U.S.C. 112, second paragraph, as assertedly being indefinite. This rejection is respectfully traversed with respect to the pending claims.

Claim 1 is canceled. Claims 18 and 22 are amended to clarify that making a determination about the health or terrestrial site mammals or the risks to mammals is based on whether the comparison of sperm parameters exceeds sperm parameter benchmarks or thresholds-for-effect. Claim 23 is amended to clarify that comparison of organ-to-body weight ratios may be used to establish an exposure-related change.

The scope of the pending claims would be reasonably ascertainable to one of ordinary skill in the art when read in light of the specification and drawings, thereby satisfying the requirements of 35 U.S.C. 112, second paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

### III. REJECTIONS UNDER 35 U.S.C. 103(a)

Claims 1, 3, 5-6, 15-16, 18, and 22-23 were rejected under 35 U.S.C. 103(a) as obvious over Ieradi et al., *Folia Zoologica*, Vol. 52, No. 1 (January 2003) in view of Ryabokon et al., *Radia. Environ. Biophys.* Vol. 44 (2005), in view of Sharma et al., *Reversible Effects of Mercuric Chloride on Reproductive Organs of the Male Mouse*, *Reproductive Toxicology*, Vol. 10, No. 2, pp. 153-59 (1996).

Ryabokon, having a publication date of 2005, is not prior art with respect to the present invention, which is entitled to the filing dates of the provisional patent applications April 11, 2003 and October 14, 2003. Moreover, the attached Declaration Under 37 C.F.R. 1.131/1.132 antedates the leradi et al. Thus, leradi et al. is also not prior art as to the present invention.

Thus, it would not have been obvious for one of ordinary skill in the art to practice the claimed methods in view of the teachings of Sharma et al. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 15-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over leradi et al. in view of Sharma et al. and further in view of Phillips et al. (Federal Facilities Environmental Journal, Vol. 13, Issue 1 (2002)) and Ryabokon et al.

As noted above, Ryabokon et al. is not prior art to the present invention. The attached 1.131/1.132 Declaration antedates the Phillips et al. article, which has a publication date of Spring 2002 (April 24, 2002). Accordingly, Phillips et al. is not prior art to the present invention.

It would not have been obvious for one of ordinary skill in the art to practice the claimed methods in view of the teachings of Sharma et al. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 19 was rejected under 35 U.S.C. 103(a) as being unpatentable over leradi et al. in view of Sharma et al. and further in view of Working (Environmental Health Perspectives, Vol. 77 (1988)). This rejection is respectfully traversed.

As noted, leradi et al. is not prior art with respect to the present invention. Thus, it would not have been obvious for one of ordinary skill in the art to practice the claimed methods in view of the combined teachings of Sharma et al. and Working. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 20-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over leradi et al. in view of Sharma et al. and further in view of Chapin et al. This rejection is respectfully traversed.

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Ieradi et al. is not prior art with respect to the present invention. Thus, it would not have been obvious for one of ordinary skill in the art to practice the claimed methods in view of the combined teachings of Sharma et al. and Chapin et al. Reconsideration and withdrawal of the rejection are respectfully requested.

#### IV. CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

/Warren Zitlau/

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Date: May 6, 2008